



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

m3207m

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6002

November 23, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Stephen C. Kimler
Medical Director
The Mountainside Hospital
Bay and Highland Avenues
Montclair, New Jersey 07042

FILE NO.: 00-NWJ-09

Dear Dr. Kimler:

During an inspection of your blood bank located at Bay and Highland Avenues, Montclair, NJ, our investigator documented deviations from the Good Manufacturing Practices Regulations for blood and blood components as prescribed in Title 21, Code of Federal Regulations (21 CFR), Subchapter F, Part 600-680. These deviations were presented to your attention on a FDA-483, List of Inspectional Observations, at the close of the inspection on October 21, 1999.

The significant observations are as follows:

1. The Mountainside Hospital Blood Bank failed to maintain accurate and reliable processing and disposition records. For example:

a. Donor record for low volume (335ml) autologous unit [REDACTED] collected on May 3, 1999, indicated that unit was to be converted into packed red blood cells, however, the unit was actually transfused as whole blood.

b. The blood bank has no documentation that an outdated autologous whole blood unit [REDACTED] collected on January 6, 1999 was discarded.

2. Unit [REDACTED] was released without the appropriate recording of the inspecting/issuing technologist, date and time the unit was issued, and the person receiving and transporting the unit, as required by Blood Bank Policy No. 705, Dispensing Blood and Components.

Warning Letter #00-NWJ-09
The Mountainside Hospital
Montclair, New Jersey 07042

3. The blood bank's standard operating procedures (SOPs) do not consistently reflect the facility's current practices. For example:

a. Policy No. 908, [REDACTED], refers to the calibration and use of the [REDACTED] Donor Scale, however the blood bank uses the manual [REDACTED]. There is no calibration SOP for the [REDACTED] scale.

4. Failure to have established procedures for the following processes.

a. No system to ensure that low volume units are labeled with an amount that is accurate within +/- 10% of the actual blood volume collected from the donor.

b. Stripping of donor blood bag tubing to prevent blood clotting in the tube.

5. The phlebotomist failed to perform the following steps during phlebotomy, as required under Policy No. 907, Autologous Blood Collection:

a. The 10% PVP iodine prep solution was not applied in a non over-lapping spiral method and solution was not allowed to stand for 30 seconds during arm preparation.

b. Hemostat was not applied to blood bag tubing prior to uncapping the needle to prevent air entering the line.

We have received your written response dated October 28, 1999, regarding the inspectional observations noted on the FDA-483. We will evaluate the implementation and the adequacy of your proposed corrective actions during the follow-up inspection of your facility.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practices Regulations.

Warning Letter #00-NWJ-09
The Mountainside Hospital
Montclair, New Jersey 07042

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This includes seizure and/or injunction, license suspension and/or revocation.

You should notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, New Jersey District Office, 10 Waterview Blvd, 3rd Floor, Parsippany, New Jersey 07054, Attention: Andrew Ciaccia, Compliance Officer.

Very truly yours,



DOUGLAS ELLSWORTH
District Director
New Jersey District Office

AC:slm